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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,873	04/18/2001	David K. Ho	208250	8939

23460 7590 07/21/2003  
LEYDIG VOIT & MAYER, LTD  
TWO PRUDENTIAL PLAZA, SUITE 4900  
180 NORTH STETSON AVENUE  
CHICAGO, IL 60601-6780

EXAMINER

KIFLE, BRUCK

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 07/21/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/743,873

Applicant(s)

Ho et al.

Examiner

Bruck Kifle, Ph.D.

Art Unit

1624

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on May 28, 2003
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 63, 65, 66, 68-70, 72, 73, 75-77, 79-81, 83-87, 90, and 91 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 63, 65, 66, 68-70, 72, 73, 75-77, 79-81, 83-87, 90, and 91 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other:

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Applicant's amendments and remarks filed 5/28/03 have been received and reviewed. Claims 63, 65, 66, 68-70, 72, 73, 75-77, 79-81, 83-87, 90 and 91 are pending in this application.

***Election/Restriction***

The search was conducted to embrace any "A" group exemplified in the specification. Applicants are advised to include the structure in page 13 into the claim if that is the genus Applicants intend to represent the group A. There is no known defined genus of a macrolide or an ansamacrolide for which the search could be expanded.

***Claim Rejections - 35 USC § 112***

Claims 63, 65, 66, 68-70, 72, 73, 75-77, 79-81, 83-87, 90 and 91 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

i) The variable X is now defined as being a polar moiety selected from "an amino acid residue, a peptide residue, a polypeptide residue and a protein residue". One cannot say what the metes and bounds of a "residue" is. Are these residues of any and all amino acids, peptides, polypeptides and proteins? It is also unclear what the metes and bounds of "A" is. There is no reason why a claim drawn in this way should not be limited to those compounds which are shown to be both new and useful. An Applicant is not entitled to a claim for a large group of compounds merely on the basis of a showing that a selected few are useful and a general suggestion of a similar utility in the others."

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Also, see *In re Surrey* 151 USPQ 724, regarding sufficiency of a disclosure for a Markush group, and MPEP 2164.03 for enablement requirements in cases directed to structure-sensitive arts such as the instant pharmaceutical arts. Note in *Surrey*, in which testing done on a group of homogeneous compounds having the same core was deemed NOT sufficient to support claims to various hetero groups of a much narrower range than is being claimed herein and located at only one position in the formula. The instant scope is undeterminable, in the millions of compounds, and therefore one compound within its scope is not remotely representative of such a scope. See MPEP 2164.03.

ii) In claims 72 and 90, the term “derivative” renders the claims indefinite. One cannot say what radical is a derivative of geldanamycin is.

Claims 77, 79 and 80 are again rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicants point to several references that indicate that some cancers express Hsp90. None of the references was received. At any rate, these cancers are broader than what the instant specification (see pages 40-43) implies could be treated. It is also noted that geldanamycin is not known to treat these cancers.

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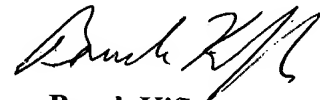
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruck Kifle whose telephone number is (703) 305-4484.

The fax phone number for this Group is (703) 308-4556 or (703) 305-3592. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

July 18, 2003

A handwritten signature in black ink, appearing to read 'Bruck Kifle', with a stylized flourish at the end.

**Bruck Kifle**  
**Primary Examiner**  
**Art Unit 1624**